REMARKS

The Examiner issued a Notice of Non-Compliant Amendment mailed on April 2, 2004 alleging that the Applicants did not provide specific references to the specification providing support to the amended and added claims. Specifically, the Examiner alleges that the Applicants "did not indicate support in the specification for amended claim language directed to "intestine" as opposed to [the] more limited term "small intestine" in [the] original claims." Notice at page 2.

Applicants submit that adequate support for the term "intestine" may be found throughout the specification and original claims. For example, the specification on page 3, lines 13-19 states:

> It has been discovered that HGF is useful for treating patients suffering from IBD. As used herein, Inflammatory Bowel Disease or IBD includes not only Chronic Ulcerative Colitis ("CUC") and Crohn's Disease ("CD") but includes necrotizing enterocolitis, severe acute gastroenteritis, chronic gastroenteritis, cholera as well as other chronic infections of the bowel.
>
> Importantly, it has been discovered that administering HGF to subjects characterized as having IBD reduces the gross and histologic lesions in these subjects.

One of ordinary skill in the art understands that IBD is an inflammatory condition that may occur anywhere in the gastrointestinal tract including the stomach, small intestine (duodenum, jejunum, and ileum), large intestine (colon), and anus. Moreover, the specification has defined IBD to include Ulcerative Colitis, Crohn's Disease, and necrotizing enterocolitis. One skilled in the art understands that Ulcerative Colitis is a disease that causes inflammation and ulcers in the lining of the large intestine; Crohn's Disease is an inflammatory condition that affects the digestive tract, including the mouth, esophagus, stomach, small and large intestine, and anus; and that

necrotizing enterocolitis primarily affects the colon and ileum, but any portion of the bowel is susceptible.

Additionally, the specification discloses that both the small and large intestine were assessed for histologic lesions for the rats in study Groups 1-3. The specification on page 5, lines 8-17 states:

> The mucosal damage and histologic lesion scores are determined by methods well known to those skilled in the art. The F344 rats of Group 1 did not demonstrate evidence of gross or histologic lesions in the small or large intestine. As can be seen in Table I, the administration of HGF significantly reduced the gross (90% decrease, $p<0.01$) and histologic (53% decrease, $p<0.01$) lesions in the Group 3 rats (HLA-B27 + HGF) when compared to the rats in Group 2 (HLA-B27) that did not receive HGF.

Therefore, Applicants submit that there is adequate support in the specification to support the term "intestine" as recited in the amended and newly added claims.

Next, the Examiner alleges that an election of species is required for the pending claims. Specifically, the Examiner alleges "[T]he claims are generic to a plurality of disclosed patentably distinct species comprising diseases involving small intestinal damage or involving inflammatory bowel disease," concluding the "methods of use of claimed compounds for treatment of each of these diseases requires a separate search, as well as enablement considerations." Notice at page 2. Applicants hereby provisionally elect, with traverse, chronic infections of the bowel as the species for the prosecution of claims 7 and 11 and provisionally elect, with traverse, immunological disorders affecting the intestine as the species for prosecution in claim 21 in the subject application.

The Examiner should be aware that the recited elements in claims 7, 21 and 27 were previously presented in dependent claim 8 which were not subject to an election of species. This requirement is a new issue not previously presented and has nothing to do with the filed

amendment. Applicants respectfully request that the Examiner accept the filed amendment and issue and office action addressing this issue.

Furthermore, in the parent case, U.S. Application Serial No. 08/932,391, now U.S. Patent No. 5,972,887, these same elements were added to the claims and found to be patentable over the same references cited against the present application by Examiner Borin. Therefore, Applicants submit that claims 7, 21 and 27 should not be subject to an election of species and are in condition for allowance.

Applicants believe that a full and complete response has been made to the Notice. Should the Examiner feel that there are any issues outstanding after consideration of this response; the Examiner is invited to contact the Applicants' undersigned representation at the number below to expedite prosecution.

Applicants believe that no extensions of time are required at this time. If extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. §1.136(a). Applicants believe that no further fees for net addition of claims are required at this time. Any fees required for further extensions of time and any fees for the net addition of claims are hereby authorized to be charged to our Deposit Account No. 23-1951.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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Date: April 30, 2004

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